IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LTD.,)))	
Counterclaim Plaintiffs,		
V.) Civ. No. 02-1512-SLR) (Consolidated)	
ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTE and LABORATOIRES FOURNIER S.A.,	(Consolidated)	
Counterclaim Defendants.)	
IMPAX LABORATORIES, INC.,))	
Counterclaim Plaintiff,))	
V.) Civ. No. 03-120-SLR) (Consolidated)	
ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTE and LABORATOIRES FOURNIER S.A.,		
Counterclaim Defendants.)	
IN RE TRICOR DIRECT PURCHASER ANTITRUST LITIGATION) Civ. No. 05-340-SLR) (Consolidated)	
IN RE TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION) Civ. No. 05-360-SLR) (Consolidated))	

Jeffrey S. Goddess of Rosenthal, Monhait & Goddess, P.A., Wilmington, Delaware.

Counsel for Louisiana Wholesale Drug Company, Inc. Of Counsel: Adam M. Steinfeld of Garwin, Gerstein & Fisher, New York, New York; David P. Smith of The Smith Foote Law Firm, LLP, Alexandria, Louisiana; John D. Radice of Kaplan Fox & Kilsheimer, New York, New York; Michael F. Heim and Russell A. Chorush of Heim, Payne & Chorush, LLP, Houston, Texas; Neill W. Clark of Berger & Montague, P.C., Philadelphia, Pennsylvania.

Jeffrey S. Goddess of Rosenthal, Monhait & Goddess, P.A., Wilmington, Delaware. Counsel for Rochester Drug Co-Operative, Inc. Of Counsel: Daniel Berger, Peter Kohn and Eric L. Cramer of Berger & Montague, P.C., Philadelphia, Pennsylvania; John D. Radice of Kaplan Fox & Kilsheimer, New York, New York; Michael F. Heim and Russell A. Chorush of Heim, Payne & Chorush, LLP, Houston, Texas.

Jeffrey S. Goddess of Rosenthal, Monhait & Goddess, P.A., Wilmington, Delaware. Counsel for Meijer Distribution, Inc. Of Counsel: David P. Germaine and Joseph M. Vanek of Vanek, Vickes & Masini, P.C., Chicago, Illinois; John D. Radice and Linda P. Nussbaum of Kaplan Fox & Kilsheimer, New York, New York; Michael F. Heim and Russell A. Chorush of Heim, Payne & Chorush, LLP, Houston, Texas; Steig D. Olson of Cohen Milstein Hausfeld & Toll, New York, New York.

Jeffrey S. Goddess of Rosenthal, Monhait & Goddess, P.A., Wilmington, Delaware. Counsel for Meijer Inc. Of Counsel: Richard J. Kilsheimer, Robert N. Kaplan, and Linda P. Nussbaum of Kaplan Fox & Kilsheimer, New York, New York; Michael F. Heim and Russell A. Chorush of Heim, Payne & Chorush, LLP, Houston, Texas; and Steig D. Olson of Cohen Milstein Hausfeld & Toll, New York, New York.

Elizabeth M. McGeever of Prickett, Jones & Elliott, P.A., Wilmington, Delaware. Counsel for Walgreen Co., Eckerd Corporation, Kroger Co., Maxi Drug, Inc. Of Counsel: Scott E. Perwin of Kenny Nachwalter, PA, Miami, Florida.

Elizabeth M. McGeever of Prickett, Jones & Elliott, P.A., Wilmington, Delaware. Counsel for CVS Pharmacy Inc., Rite Aid Corporation, Rite Aid Headquarters Corporation. Of Counsel: Joseph T. Lukens and Steve D. Shadowen of Hangley Aronchick Segal & Pudlin, Philadelphia, Pennsylvania.

Elizabeth M. McGeever of Prickett, Jones & Elliott, P.A., Wilmington, Delaware. Counsel for American Sales Company, Inc.

A. Zachary Naylor of Chimicles & Tikellis, LLP, Wilmington, Delaware; Daniel J. Brown of McCarter & English, LLP, Wilmington, Delaware. Counsel for Painters District Council No. 30 Health & Welfare Fund. Of Counsel: Bernard NMN Persky and Kellie Safar of Labaton Sucharow, New York, New York; David A. Kalow of Kalow & Springut, LLP, New York, New York; David S. Nalven and Gregory H. Matthews of Hagens Berman Sobol Shapiro, LLP, Cambridge, Massachusetts; Marvin A. Miller of Miller Law, LLC, Chicago, Illinois.

- A. Zachary Naylor of Chimicles & Tikellis, LLP, Wilmington, Delaware. Counsel for Richard G. Wilde. Of Counsel: Patrick E. Cafferty of Cafferty Faucher, LLP, Philadelphia, Pennsylvania.
- A. Zachary Naylor of Chimicles & Tikellis, LLP, Wilmington, Delaware. Counsel for Vista Healthplan, Inc. Of Counsel: Christopher J. McDonald of Labaton Sucharow, New York, New York; Kevin B. Love of Hanzman, Criden & Love, Miami, Florida; Patrick E. Cafferty of Cafferty Faucher, LLP, Philadelphia, Pennsylvania.
- A. Zachary Naylor of Chimicles & Tikellis, LLP, Wilmington, Delaware. Counsel for Ross Love. Of Counsel: Patrick E. Cafferty of Cafferty Faucher, LLP, Philadelphia, Pennsylvania.
- A. Zachary Naylor of Chimicles & Tikellis, LLP, Wilmington, Delaware. Counsel for Allied Services Division Welfare Fund. Of Counsel: Bryan L. Clobes of Cafferty Faucher, LLP, Philadelphia, Pennsylvania; Patrick E. Cafferty of Cafferty Faucher, LLP, Philadelphia, Pennsylvania.
- A. Zachary Naylor of Chimicles & Tikellis, LLP, Wilmington, Delaware. Counsel for Hector Valdes. Of Counsel: Patrick E. Cafferty of Cafferty Faucher, LLP, Philadelphia, Pennsylvania.
- Michael I. Silverman of Silverman & McDonald, Wilmington, Delaware; A. Zachary Naylor of Chimicles & Tikellis, LLP, Wilmington, Delaware. Counsel for Pennsylvania Employees Benefit Trust Fund. Of Counsel: Jeffrey L. Kodroff and Theodore M. Lieverman of Spector, Roseman & Kodroff, P.C., Philadelphia, Pennsylvania; Patrick E. Cafferty of Cafferty Faucher, LLP, Philadelphia, Pennsylvania.
- Patrick Francis Morris of Morris & Morris LLC, Wilmington, Delaware; A. Zachary Naylor of Chimicles & Tikellis, LLP, Wilmington, Delaware. Counsel for Diana Kim. Of Counsel: Joseph Goldberg of Freedman Boyd Hollander Goldberg & Ives, Albuquerque, New Mexico; Patrick E. Cafferty of Cafferty Faucher, LLP, Philadelphia, Pennsylvania.
- A. Zachary Naylor of Chimicles & Tikellis, LLP, Wilmington, Delaware. Counsel for Philadelphia Federation of Teachers Health and Welfare Fund and Cindy Cronin. Of Counsel: Patrick E. Cafferty of Cafferty Faucher, LLP, Philadelphia, Pennsylvania.
- A. Zachary Naylor of Chimicles & Tikellis, LLP, Wilmington, Delaware; Michael I. Silverman of Silverman & McDonald, Wilmington, Delaware. Counsel for Charles M. Shain. Of Counsel: Ann D. White of Ann D. White Law Offices, Jenkintown, Pennsylvania; E. Elizabeth Ferguson of Wolf Popper, LLP, New York, New York; Patrick E. Cafferty of Cafferty Faucher, LLP, Philadelphia, Pennsylvania.
- A. Zachary Naylor of Chimicles & Tikellis, LLP, Wilmington, Delaware; Michael I. Silverman of Silverman & McDonald, Wilmington, Delaware. Counsel for Sandra Krone. Of Counsel: Patrick E. Cafferty of Cafferty Faucher, LLP, Philadelphia,

Pennsylvania.

A. Zachary Naylor of Chimicles & Tikellis, LLP, Wilmington, Delaware; Michael I. Silverman of Silverman & McDonald, Wilmington, Delaware. Counsel for Elaine M. Pullman. Of Counsel: Thomas M. Sobol of Hagens Berman Sobol Shapiro, LLP, Cambridge, Massachusetts; Patrick E. Cafferty of Cafferty Faucher, LLP, Philadelphia, Pennsylvania.

A. Zachary Naylor of Chimicles & Tikellis, LLP, Wilmington, Delaware; Michael I. Silverman of Silverman & McDonald, Wilmington, Delaware. Counsel for Neil Perlmutter, Helena Perlmutter, and Lula Ramsey. Of Counsel: Patrick E. Cafferty of Cafferty Faucher, LLP, Philadelphia, Pennsylvania.

Lynn A. Iannone of Silverman McDonald & Friedman, Wilmington, Delaware; A. Zachary Naylor of Chimicles & Tikellis, LLP, Wilmington, Delaware. Counsel for Local 28 Sheet Metal Workers. Of Counsel: Jason J. Thompson of Charfoos & Christensen, P.C., Detroit, Michigan; Patrick E. Cafferty of Cafferty Faucher, LLP, Philadelphia, Pennsylvania.

Jonathan L. Parshall of Murphy, Spadaro & Landon, Wilmington, Delaware. Counsel for Pacificare Health Systems, Inc. Of Counsel: Garrick B. Pursley of Susman Godfrey, LLP, Dallas, Texas.

A. Zachary Naylor of Chimicles & Tikellis, LLP, Wilmington, Delaware. Counsel for Alberto Litter. Of Counsel: Lance A. Harke of Harke & Clasby, LLP, Miami, Florida; Patrick E. Cafferty of Cafferty Faucher, LLP, Philadelphia, Pennsylvania.

Josy W. Ingersoll and Karen Elizabeth Keller of Young, Conaway, Stargatt & Taylor, Wilmington, Delaware. Counsel for Teva Pharmaceuticals U.S.A., Inc.

Josy W. Ingersoll of Young, Conaway, Stargatt & Taylor, Wilmington, Delaware. Counsel for Teva Pharmaceuticals Industries, Ltd and Novopharm Limited.

Mary Matterer and Richard Herrmann of Morris James, LLP, Wilmington, Delaware. Counsel for Impax Laboratories, Inc.

Mary B. Graham and James Walter Parrett, Jr. of Morris, Nichols, Arsht & Tunnell, LLP, Wilmington, Delaware. Counsel for Abbott Laboratories.

Anne Shea Gaza and Frederick L. Cottrell, III of Richards, Layton & Finger, Wilmington, Delaware. Counsel for Fournier Industrie et Sante. Of Counsel: Bradley J. Demuth of Skadden, Arps, Slate, Meagher & Flom, LLP, New York, New York; David S. King, Anne P. Davis and Sonia K. Pfaffenroth of Arnold & Porter, LLP, Washington, D.C.

Anne Shea Gaza of Richards, Layton & Finger. Counsel for Laboratories Fournier, S.A. Of Counsel: David S. King of Arnold & Porter, LLP, Washington, D.C.

MEMORANDUM OPINION

Dated: August 18, 2008 Wilmington, Delaware ROBINSON, District Judge

I. INTRODUCTION

Presently before the court is plaintiffs' Louisiana Wholesale Drug Co., Inc. ("LWD"), Rochester Drug Co-Operative, Inc. ("RDC") and Meijer, Inc. and Meijer Distribution, Inc. (together, "Meijer") (collectively, the "direct purchaser plaintiffs" or the "proposed DPP class")) motion for class certification pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3).1 (D.I. 106, D.I. 107 at 1-2) Also before the court is the indirect purchaser plaintiffs' motion for class certification pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2) and 23(b)(3).2 (D.I. 116) Defendants are Abbott Laboratories ("Abbott") and Fournier Industrie et Sante and Laboratories Fournier S.A. (together, "Fournier") (collectively, "defendants"). (D.I. 107 at 1) The direct purchaser and indirect purchaser plaintiffs assert that defendants engaged in anticompetitive conduct. (Id.) More specifically, they allege that defendants, through an overarching scheme, impeded the market entry of the generic version of TRICOR®, a brand name drug used to control levels of cholesterol and triglycerides. (See id.; Civ. No. 05-360, D.I. 24) In particular, direct and indirect purchaser plaintiffs contend that defendants manipulated the statutory framework that regulates pharmaceutical drugs to maintain

¹Other named plaintiffs in this action, Civ. No. 05-340-SLR, are Walgreen Co., Eckerd Corp., Kroger Co., Maxi Drug, Inc., CVS Pharmacy Inc., Rite Aid Corp., Rite Aid Headquarters Corp., and American Sales Company, Inc. Eckerd Corp. has preemptively opted out of the proposed class. (See D.I. 190 at 7)

²The indirect purchaser plaintiffs are Painters' District Council No. 30 Health and Welfare Fund, Richard G. Wilde, Vista Health Plan, Inc., Ross Love, Pennsylvania Employees Benefit Trust Fund, Allied Services Division Welfare Fund, Hector Valdes, Diana Kim, Elaine M. Pullman, Neil Perlmutter, Helena Perlmutter, Lula Ramsey, Philadelphia Federation of Teachers Health and Welfare Fund, Cindy Cronin, Charles Shain, Sandra Krone, Local 28 Sheet Metal Workers and Alberto Litter (collectively, the "indirect purchaser plaintiffs").

monopoly power. (See id.) For the reasons that follow, the direct purchaser plaintiffs' motion (D.I. 106) is granted. The indirect purchaser plaintiffs' motion (Civ. No. 05-360, D.I. 116) is [granted in part and denied in part].³

II. BACKGROUND⁴

Plaintiffs assert that defendants instituted a multi-faceted scheme, which manipulated the statutory framework as set forth in the Hatch Waxman Act, to maintain a monopoly position in the market, consisting of: (1) "sham" litigations; (2) product conversions; and (3) other intentional wrongful behavior designed to further a monopoly, as discussed in more detail below.

TRICOR® is a drug that is used to reduce high-levels of low-density lipoprotein cholesterol ("LDL-C") or "bad cholesterol," and of triglycerides by promoting the dissolution and elimination of fat particles in the blood. (Id. at ¶ 42) TRICOR® increases levels of high-density lipoprotein cholesterol ("HDL-C") or "good cholesterol," and reduces LDL-C in patients with primary hypercholesterolemia (high bad cholesterol) or mixed dyslipidemia (high bad cholesterol and high triglycerides). (Id.) TRICOR® also effectively reduces triglycerides in patients with hypertriglyceridemia (high triglycerides). (Id.) The active pharmaceutical ingredient in TRICOR® is fenofibrate. (Id.)

³Pursuant to the court's order of this same date, the court need not address the indirect purchaser plaintiffs' arguments concerning their non-federal claims.

⁴The court, for purposes of the background section, assumes familiarity with the Hatch Waxman framework ("Hatch Waxman Act"), 21 U.S.C. §§ 301 et seq., and takes the allegations in the direct purchaser plaintiffs' complaint as true. (Civ. No. 05-340, D.I. 29) Unless otherwise noted, citations to the record refer to those docket item numbers as reflected in the direct purchaser action. Civ. No. 05-340.

Fenofibrate is a fibrate.⁵ (<u>Id.</u> at ¶ 43) Fibrates, statins, bile acid sequestrants and niacin are categories of cholesterol-lowering drugs. (<u>Id.</u>) Each category has different side effects and different efficacy profiles for reducing LDL-C, raising HDL-C and lowering triglycerides. (<u>Id.</u>) According to plaintiffs, a cholesterol-lowering drug from one category is not reasonably interchangeable with a drug from another category; consequently, TRICOR® occupies an unique niche, defined by its efficacy in controlling levels of HDL-C, LDL-C and triglycerides. (<u>Id.</u> at ¶ 45)

In 1997, Fournier granted Abbott an exclusive license to U.S. Patent No. 4,895,726 (the "Curtet Patent" or "the '726 patent"), which claims a formulation of fenofibrate. (Id. at ¶ 46) Defendants submitted separate New Drug Applications ("NDA") for three strengths of branded fenofibrate capsules. (Id.) The FDA approved the TRICOR® 67 mg capsule NDA on February 9, 1998 and the TRICOR® 134 mg and 200 mg capsule NDAs on June 30, 1999. (Id.) Defendants marketed each of these capsule products (collectively, "TRICOR®-A") shortly after receiving FDA approval and successfully sold TRICOR®-A throughout 2000 and 2001. (Id.) In connection with the TRICOR®-A fenofibrate capsules, Abbott submitted the '726 patent to the FDA for listing in the Orange Book. (Civ. No. 05-360, D.I. 24 at ¶ 49)

On December 14, 1999, Novopharm Limited ("Novopharm"), which was

⁵Other fibrates include clofibrate and gemfibrozil. (D.I. 29 at ¶ 44)

⁶Unless otherwise denoted, plaintiffs do not differentiate between defendants and, consequently, neither does the court. (See D.I. 29 at ¶ 46)

subsequently acquired by Teva, filed an Abbreviated New Drug Application ("ANDA") with the FDA. (Id. at ¶ 62) Teva's ANDA requested approval to market generic fenofibrate 67 mg capsules (the "Teva Capsule ANDA") before the expiration of the '726 patent. (Id.) Novopharm later amended the Teva Capsule ANDA to request approval to market generic fenofibrate 134 mg and 200 mg capsules. (Id.) In connection with the Teva Capsule ANDA, Novopharm certified under Paragraph IV that the proposed generic fenofibrate capsule did not infringe the '726 patent. (Id.) On May 9, 2000, Impax also filed an ANDA for TRICOR®-A (the "Impax Capsule ANDA"), similarly seeking to market its fenofibrate capsules prior to the expiration of the '726 patent. (Id.) Impax certified under Paragraph IV that its product did not infringe the '726 patent. (Id.)

On or about April 7, 2000, August 18, 2000 and March 19, 2001, respectively, defendants initiated a series of infringement actions in the United States District Court for the Northern District of Illinois against Teva, its subsidiary Novopharm, and Impax alleging that the generic manufacturers had infringed the '726 patent under 35 U.S.C. §

⁷Teva Pharmaceuticals U.S.A., Inc. and Teva Pharmaceuticals Industries, Ltd. (together "Teva") are parties in a related action, Civ. No. 02-1512-SLR. As discussed in more detail below, Teva, a generic manufacturer, sought to market a generic version of TRICOR®.

⁸In April 2000, Teva acquired Novopharm, making it a Teva entity. (Civ. No. 05-360, D.I. 24 at ¶ 52) Novopharm was joined as a counterclaim plaintiff in related litigation, Civ. No. 02-1512. (Civ. No. 02-1512, D.I. 426)

⁹In other words, Teva's Capsule ANDA requested approval for all formulations of TRICOR®-A.

¹⁰Impax Laboratories, Inc. is a party in a related action, Civ. No. 03-120, and also sought to manufacture a generic version of TRICOR®.

271(e)(2) (these three suits, collectively, referred to as the "Illinois Litigation"). (Id. at ¶ 65) These suits, under the Hatch-Waxman Act, imposed thirty-month stays on FDA approval for Teva's and Impax's products. (Id. at ¶ 66)

On March 19, 2002, the Illinois district court granted Teva's motion for summary judgment of non-infringement and the Federal Circuit subsequently affirmed. (<u>Id.</u> at ¶¶ 68, 73-75) While the appeal before the Federal Circuit was pending, Teva received FDA approval to market its 67 mg, 134 mg and 200 mg capsules on April 9, 2002. (<u>Id.</u> at ¶ 76) Teva's 134 mg and 200 mg capsules entered the market shortly thereafter. (<u>Id.</u>)

Defendants, during the pendency of the Illinois Litigation, started to develop a tablet formulation of TRICOR®, in 54 mg and 160 mg strengths ("TRICOR®-B"). (Id. at ¶ 79) On September 4, 2001, defendants obtained FDA approval to market TRICOR®-B.¹⁴ (Id. at ¶ 80) Defendants marketed the TRICOR®-B tablets, stressing that TRICOR®-B had an additional indication for HDL effect, while TRICOR®-A had not

¹¹The FDA, on February 20, 2002, granted Impax tentative approval for its fenofibrate capsules. (D.I. 29 at ¶ 67)

¹²Teva received final approval from the FDA for its 134 mg and 200 mg capsules on April 9, 2002. (D.I. 29 at ¶ 76) The FDA tentatively approved Teva's 67 mg capsule on April 19, 2002. (Id.) Impax received final FDA approval to market its fenofibrate capsule products on October 28, 2003. (Id. at ¶ 77)

¹³Plaintiffs allege that the delay afforded by the stays in the Illinois litigation had granted defendants time to execute their market switch strategy or "Life Cycle Management" strategy and, specifically, to convert TRICOR®-A's formulation from a capsule to a tablet. (D.I. 29 at ¶¶ 76, 78, 93)

¹⁴On this date, the Illinois Litigation was ongoing and, consequently, the thirtymonth stays remained in effect. (D.I. 29 at ¶ 80)

been approved for HDL treatment. (Civ. No. 05-360, D.I. 24 at ¶ 53) According to direct purchaser plaintiffs, however, TRICOR®-B did not provide the public with a better or improved product because it contained the same drug as the earlier-approved capsules, was therapeutically equivalent, and bioequivalent to the capsules. (D.I. 29 at ¶ 80) In particular, both capsules and tablets had the same HDL effect. (Civ. No. 05-360, D.I. 24 at ¶ 53)

Defendants then stopped all new sales of TRICOR®-A and directed their sales force to sell only TRICOR®-B. (Id. at ¶ 81) Defendants, in or about December 2001, also caused TRICOR®-A to be listed as obsolete in the National Drug Data File. (Id. at ¶ 85c) The obsolete listing of TRICOR®-A caused Teva's corresponding generic version of TRICOR®-A to be identified as a brand drug and, consequently, resulted in a higher co-payment for Teva's generic product. (Id.)

On or around June 17, 2002, Teva filed with the FDA an ANDA for its generic fenofibrate 54 mg and 160 mg tablets (the "Teva Tablet ANDA"), along with a Paragraph IV certification that its tablets did not infringe the '726 patent, and did not infringe two additional patents that defendants had listed in the Orange Book as covering TRICOR®-B. ¹⁶ (Id. at ¶ 97) Teva amended its ANDA on July 29, 2003 and

¹⁵Patients' prescriptions generally are paid for by a third party, such as an insurer or HMO. (D.I. 29 at ¶ 85) Most third party payors subscribe to a data service provided by First Data Bank, which indicates whether a particular drug is a branded or generic drug. (<u>Id.</u>) This information is used to set co-payment levels for the patients. (<u>Id.</u>) Specifically, higher co-payments generally are set for branded drugs than for generic drugs. (<u>Id.</u>)

¹⁶These patents are U.S. Patent No. 6,074,670 ("the '670 patent"), issued on June 13, 2000 and U.S. Patent No. 6, 277,405 ("the '405 patent"), issued on August 21, 2001. (D.I. 29 at ¶ 97)

December 17, 2003, respectively, by filing two additional Paragraph IV certifications, one for U.S. Patent 6,589,552 ("the '552 patent") and one for U.S. Patent No. 6,652,881 ("the '881 patent"). (Id. at ¶ 98)

In three separate complaints filed in the United States District Court for the District of Delaware, Abbott alleged that Teva had infringed the five patents to which Teva had filed Paragraph IV certifications. 17 (Id. at ¶ 99) The first and second complaints, pursuant to the Hatch-Waxman Act, imposed two successive thirty-month stays and thus delayed FDA approval of Teva's tablet ANDA. (Id. at ¶ 100) The first thirty-month stay, triggered by the first complaint, expired on February 26, 2005. (Id.) The second stay expired in February 2006. 18 (Id.) Impax filed its ANDA (the "Impax Tablet ANDA") for fenofibrate tablets in or around December 2002. (Id. at ¶ 101) Impax similarly submitted Paragraph IV certifications that its tablets did not infringe the '726, the '670 and the '405 patents. (Id.) On January 23, 2003, defendants sued Impax for patent infringement, resulting in another thirty-month stay. (Id.) The issuance and Orange Book Listing of the '552 patent resulted in an additional infringement case against Impax, as well as a thirty-month stay. 19 (Id.)

¹⁷The first complaint, filed on October 4, 2002, alleged infringement of the '726 patent, the '670 patent, and the '405 patent. (D.I. 29 at ¶ 99) The second complaint, filed on August 29, 2003, asserted infringement of the '552 patent. (<u>Id.</u>) Finally, the third complaint was filed on January 22, 2004 and alleged infringement of the '881 patent. (Id.)

¹⁸The third complaint did not trigger a third stay because of amendments made to the Hatch Waxman Act, which limited the amount of stays obtained per ANDA.

¹⁹The listing of the '881 patent resulted in another infringement suit against Impax, however, no stay was associated with this suit. (D.I. 29 at ¶ 101)

On March 5, 2004, the FDA granted tentative approval to Impax's and Teva's Tablet ANDAs. (Id. at ¶ 102) Absent the thirty-month stays in effect, Impax and Teva would have received final approval on March 5, 2004. (Id.) The various infringement suits in Delaware against Teva and Impax were consolidated (the "Delaware Litigation"). (Id. at ¶ 103) Trial was scheduled to begin on December 6, 2004, but was moved back to June 6, 2005 to allow for filing of the infringement actions related to the '552 patent. (Id.) Defendants, with less than a month before trial, sought voluntary dismissal of all pending Delaware infringement actions. (Id.)

During the pendency of the Delaware Litigation, defendants implemented a second market switch in late 2004, eight months after the generic manufacturers received tentative approval from the FDA for their Tablet ANDAs. (Id. at ¶ 104)

According to direct purchaser plaintiffs, the stated goal of the second conversion was "to convert over 95% of the fenofibrate business to the new TRICOR® . . . within 6 months," so that the market would be converted to a second tablet formulation ("TRICOR®-C") before the generic versions of TRICOR®-B received FDA approval. (Id. at ¶ 106) The second conversion was executed with a series of steps similar to those defendants had employed in the first conversion. (Id.)

Defendants developed TRICOR®-C during the delay in generic entry caused by the first conversion and the Delaware Litigation. (<u>Id.</u> at ¶ 107) The FDA approved defendants' NDA for TRICOR®-C, in 48 mg and 145 mg strengths, on November 5, 2004. (<u>Id.</u>) TRICOR®-C includes the same ingredients and is indicated for the same uses as the TRICOR®-B tablet formulation; however, the new dosage strengths of TRICOR®-C precluded generic substitution of those approved from TRICOR®-B. (<u>Id.</u>)

TRICOR®-C allowed patients the convenience of taking TRICOR® with meals, however, these tablets did not provide any medical or clinical benefits that were not already provided by either TRICOR®-A or TRICOR®-B. (Id. at ¶ 109)

III. STANDARD

A district court has broad discretion to grant or deny class certification. <u>See</u>

<u>Eisenberg v. Gagnon</u>, 766 F.2d 770, 785 (3d Cir. 1985). The court does not inquire into the merits of a lawsuit when determining whether it may be maintained as a class action. <u>See Eisen v. Carlisle and Jacquelin</u>, 417 U.S. 156, 177 (1974). However, the court must conduct a limited preliminary inquiry, examining beyond the pleadings, to determine whether common evidence could suffice to make out a prima facie case for the class. <u>See General Tel. Co. of Southwest v. Falcon</u>, 457 U.S. 147, 160 (1982) ("[T]he class determination generally involves considerations that are enmeshed in the factual and legal issues comprising the plaintiff's cause of action.") (internal citation omitted); <u>Newton v. Merrill Lynch</u>, <u>Pierce</u>, <u>Fenner & Smith</u>, <u>Inc.</u>, 259 F.3d 154, 167 (3d Cir. 2001) ("[C]ourts may delve beyond the pleadings to determine whether the requirements for class certification are satisfied.").

The party seeking class certification bears the burden of establishing that certification is warranted under the circumstances. In re ML-Lee Acquisition Fund II, L.P. Sec. Litig., 848 F. Supp. 527, 557 (D. Del. 1994). Rule 23 of the Federal Rules of Civil Procedure sets forth the requirements for certification of a class. Under Rule 23(a), these requirements are: (1) the class is so numerous that joinder of all members is impracticable ("numerosity"); (2) there are questions of law or fact common to the class ("commonality"); (3) the claims or defenses of the representative parties are

typical of the claims or defenses of the class ("typicality"); and (4) the representative parties will fairly and adequately protect the interests of the class. In re Warfarin Sodium Antitrust Litigation, 212 F.R.D. 231, 246 (D. Del. 2002). Plaintiff bears the burden to "establish that all four requisites of Rule 23(a) and at least one part of Rule 23(b) are met." Baby Neal v. Casey, 43 F.3d 48, 55 (3d Cir. 1994).

Under Rule 23(b)(3), two additional requirements must be met for a class to be certified: (a) common questions must predominate over any questions affecting only individual members; and (b) class resolution must be superior to other available methods for the fair and efficient adjudication of the controversy. Amchem Prods. Inc. v. Windsor, 521 U.S. 591, 613 (1997). Relevant to this inquiry are the following factors: (a) the interest of members of the class individually controlling the prosecution or defense of separate actions; (b) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (c) the desirability or undesirability of concentrating litigation of the claims in the particular forum; (d) the difficulties likely to be encountered in the management of the class action. Id. at 615-16. The Supreme Court has noted that the dominant purpose behind certifying Rule 23(b)(3) cases is to vindicate the rights of people who individually would be without the strength to bring their opponents into court; it overcomes the problem of small recoveries, which do not provide enough incentive for individual actions to be prosecuted. Id. at 617.

IV. DISCUSSION²⁰

²⁰The generic manufacturers, Teva and Impax, take no position on the merits of the class certification motions before the court. (Civ. No. 02-1512, D.I. 600) Teva and

A. Direct Purchaser Plaintiffs

The proposed DPP class is as follows: "All persons or entities in the United States who purchased T[RICOR]® in any form directly from any of the defendants at any time during the period April 9, 2002, through the present."²¹ (D.I. 107 at 2) The functional categories of the proposed DPP class include, inter alia, pharmaceutical wholesalers, chain retailers and independent retail pharmacies, and pharmacy benefit managers. (See D.I. 192, ex. 3 at ¶ 22) The direct purchaser plaintiffs assert two claims against defendants for violations of the Sherman Act pursuant to 15 U.S.C. §§ 1, 2. (D.I. 29 at ¶¶ 160-71, 172-84) More specifically, the proposed DPP class contends that defendants violated § 2 of the Sherman Act²² because they delayed and excluded generic competition through their overarching scheme and that defendants violated § 1 of the Sherman Act²³ through their alleged conspiracy to execute their overarching

Impax, however, do note that a number of the arguments asserted in defendants' supplemental brief (Civ. No. 05-340, D.I. 382) rely on factual assumptions that are disputed. (Civ. No. 02-1512, D.I. 600 at 1) In particular, Teva and Impax point to the factual assertions concerning relevant market and the substitutability between TRICOR® and other medications. (Id.)

²¹Excluded from the proposed DPP class are defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities. (D.I. 107 at 1 n.2)

²²"Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding \$100,000,000 if a corporation, or, if any other person, \$1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court." 15 U.S.C. § 2.

²³"Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is

scheme. (<u>Id.</u>) The proposed DPP class moves for certification pursuant to Fed. R. Civ. P. 23(a) and (b)(3). (D.I. 107 at 2)

1. Numerosity²⁴

To be certified, the class must be "so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a)(1). "No minimum number of plaintiffs is required to maintain a suit as a class action, but generally if the named plaintiff demonstrates that the potential number of plaintiffs exceeds 40, the first prong of Rule 23(a) has been met." Stewart v. Abraham, 275 F.3d 220, 227-28 (3d Cir. 2001). In the case at bar, Joseph Edward Fiske ("Fiske"), Abbott's Rule 30(b)(6) representative, stated that direct purchasers of TRICOR® consisted of 27-30 separate wholesalers and other entities, including chain drug stores and some managed care entities. (D.I. 109, ex. A at 140-41). Dr. Jeffrey J. Leitzinger ("Dr. Leitzinger"), direct purchaser plaintiffs' proffered expert, estimates the number of class members at approximately 300.²⁵ (Id., ex. B at 34 n.77) In addition to the above identified numbers, the court notes that the proposed DPP class is broadly drawn, which suggests, once all class members are identified, that the class will be so numerous as to make joinder impracticable. Accordingly, the

declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding \$100,000,000 if a corporation, or, if any other person, \$1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court." 15 U.S.C. § 1.

²⁴Defendants do not contest that plaintiffs have demonstrated numerosity. (See D.I. 190)

²⁵This estimation is based on a preliminary review of Abbott's transactional sales data. (D.I. 107 at 16)

proposed DPP class satisfies the numerosity requirement.²⁶

2. Commonality

Commonality requires that class members share a single common issue of law or fact. See Baby Neal, 43 F.3d at 56. The proposed DPP class alleges a common course of conduct which, it contends, had a general effect on the market in that defendants' conduct artificially raised the price of TRICOR®. Specifically, the direct purchaser plaintiffs assert that at least five questions of law or fact are common to the proposed DPP class: (1) whether defendants maintained monopoly power by delaying generic entry; (2) whether direct proof of defendants' monopoly power is available and, if available, whether it is sufficient to prove defendants' monopoly power without the need to also define a relevant market; (3) to the extent a relevant market must be defined, what the relevant market is; (4) whether defendants' activities have substantially affected interstate commerce; and (5) whether, and to what extent. defendants' conduct caused antitrust injury to the business or property of plaintiffs and the members of the proposed class and, if so, the appropriate measure of damages. (See D.I. 29 at ¶ 28) The direct purchaser plaintiffs also contend, and defendants do not dispute, that all class members will use the same evidence to prove the alleged conspiracy and improper maintenance of monopoly power.²⁷ (See D.I. 107 at 16) The

²⁶Where, as here, potential class members are from disparate geographical areas, this also weighs towards class certification. See Marian Bank v. Electronic Payment Services, Inc., Civ. No. 95-614, 1997 WL 811552, at *15 (D. Del. Dec. 30, 1997).

²⁷ Discussed in more detail <u>infra</u>, regarding Rule 23(b)(3)'s predominance requirement.

proposed DPP class has demonstrated the commonality requirement because these questions generally focus on defendants' conduct and, as such, are common to all members of the class. See In re Warfarin Sodium Antitrust Litigation, 391 F.3d 516, 529 (3d Cir. 2004) (stating that allegations for a violation of § 2 of the Sherman Act "naturally raise several questions of law and fact common to the entire class); In re Linerboard Antitrust Litigation, 305 F.3d 145, 151-52 (3d Cir. 2002) (finding that, when the inquiry focuses on defendants' actions, a conspiracy claim pursuant to § 1 of the involves common issues of fact and law).

3. Typicality²⁸

Typicality requires that "the claims . . . of the representative parties are typical of the claims . . . of the class," not that the claims are identical. See Fed. R. Civ. P. 23(a)(3); see also In re Warfarin, 391 F.3d at 531-32. "The typicality inquiry centers on whether the interests of the named plaintiffs align with the interests of the absent members." Stewart, 275 F.3d at 227-28. More specifically, "[f]actual differences will not render a claim atypical if the claim arises from the same event or practice or course of conduct that gives rise to the claims of the [absent] class members, and if it is based on the same legal theory." Id. (alteration in original) (citing Hoxworth v. Blinder, Robinson & Co., Inc., 980 F.2d 912, 923 (3d Cir.1992)). The proposed DPP class contends that typicality is satisfied because "all class members' claims arise out of a common wrong: a core pattern of alleged anti-competitive conduct that, if true, would have similarly injured each of them by artificially raising or stabilizing the price of

²⁸Defendants do not dispute that plaintiffs have satisfied typicality.

fenofibrate." (D.I. 107 at 18) As discussed above, the direct purchaser plaintiffs' claims do arise out of the same course of alleged conduct, the "overarching scheme" employed by defendants, causing each class member to pay supracompetitive prices of TRICOR®. Any claims from absent class members also will arise out of the same course of conduct and alleged overpayment. See In re Warfarin, 391 F.3d at 531-32. Typicality, therefore, is satisfied.

4. Adequacy

Rule 23(a) also requires that the representative class members "fairly and adequately protect the interests of the class." See Fed. R. Civ. P. 23(a)(4). This inquiry "has two components designed to ensure that absentees' interests are fully pursued." See In re Warfarin, 391 F.3d at 532 (citing Georgine v. Amchem Prods., Inc., 83 F.3d 610, 630 (3d Cir.1996), aff'd, Amchem, 521 U.S. at 591). "First, the adequacy inquiry 'tests the qualifications of the counsel to represent the class.'" Id. (quoting In re Prudential Ins. Co. America Sales Practice Litigation Agent Actions, 148 F.3d 283, 313 (3d Cir. 1998)). "Second, it seeks 'to uncover conflicts of interest between named parties and the class they seek to represent." Id. (quoting Prudential, 148 F.3d at 313).

a. Qualifications of Counsel

Counsel for the proposed DPP class have submitted firm resumes demonstrating that counsel possesses the competence, skill and experience necessary to prosecute the class' claims. (D.I. 109, exs. F-K); see Jerry Enterprises of Gloucester County, Inc. v. Allied Beverage Group, L.L.C., 178 F.R.D. 437, 446 (D.N.J. 1998). In particular, counsel have participated in several class action antitrust suits, including

actions relating to generic and brand pharmaceutical drugs which share circumstances similar to the case at bar. (See id.) The direct purchaser plaintiffs have sufficiently demonstrated this requirement.

b. Absence of Conflict

The proffered representative direct purchaser plaintiffs are two drug wholesalers, LWD and RDC, and an assignee of a drug wholesaler, Meijer.²⁹ (D.I. 29 at ¶¶ 16-18; D.I. 107 at 19) The proposed DPP class asserts that these representative plaintiffs will adequately represent the class because all plaintiffs share a strong interest in establishing the liability of defendants and seek the same type of damages for the same type of injury. (D.I. 107 at 20) That is, each class member has the same interest as each class representative in that all seek to establish defendants' anti-competitive conduct, which resulted in each class member's payment of an overcharge that they now seek to recover. (See id.)

Defendants challenge the adequacy of the proffered representatives. (See D.I. 190 at 20, 21 (noting "conflict within the class")) In particular, the named plaintiffs are

²⁹Defendants briefly contest the adequacy of Meijer as a proper representative. (D.I. 190 at 25) In particular, they argue that it is improper for an assignee to represent the class and thus to "treat class membership as a transferable asset." See In re Public Offering Fee Antitrust Litigation, Civ. Nos. 98-7890, 00-7804, 2006 WL 1026653, at * 4 (S.D.N.Y. Apr. 18, 2006). In this regard, the court notes that defendants do not challenge the adequacy of LWD and RDC as representatives and that the Third Circuit has not adopted the position advanced by defendants. See In re Fine Paper Litigation, 632 F.2d 1081, 1091 (3d Cir. 1980) (noting that an assignee's claims are, by definition, identical to those of the class); see also In re Cardizem CD Antitrust Litigation, 200 F.R.D. 297, 306 (E.D. Mich. 2001) (stating that there is no inherent conflict between an assignee of a claim and its respective class). The court, in these circumstances, sees no conflict between Meijer's interests and the class, based solely on Meijer's status as an assignee.

small regional wholesalers who, defendants assert, stand in sharp contrast to the "Big Three" wholesalers, also putative members of the class who account for approximately ninety percent of the wholesale prescription drug distribution in the United States. (Id. at 21) Based on differing price strategies, defendants contend that the "Big Three" may have benefitted from an overcharge whereas the named plaintiffs did not.³⁰ Defendants also assert that a market condition, called "generic bypass", where retailers purchase generic products directly from manufacturers and from small regional wholesalers, thereby bypassing the "Big Three," means that the "Big Three" actually may have lost revenue in the "but for" world. (Id.)

These arguments are irrelevant under direct purchaser plaintiffs' overcharge theory and create no conflict, real or otherwise. Direct purchasers may recover the amount of their overcharges irrespective of what happens after the overcharge is paid. See Hanover Shoe, 392 U.S. at 489. Commonly known as "downstream effects," consideration of these net effects of the challenged conduct on direct purchasers could potentially weaken enforcement and undermine the very purpose of the antitrust laws. See Illinois Brick Co. v. Illinois, 431 U.S. 720, 725 (1977). Based on the foregoing, the court concludes that the proffered representatives are adequate, counsel is experienced in antitrust litigation and no conflicts exist within the class; consequently, plaintiffs have demonstrated that the adequacy requirement is satisfied. See In re

³⁰In particular, defendants assert that the "Big Three" employ a "cost-plus" pricing strategy. This results in higher profits because as the acquisition cost increases so does the cost-plus price. (D.I. 190 at 21)

5. Predominance³¹

At the outset, the court notes that the Supreme Court has stated that the predominance requirement is "readily met" in cases alleging violations of the antitrust laws. Amchem, 521 U.S. at 625. Rule 23(b)(3)'s predominance element requires that common issues predominate over issues affecting only individuals and tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation.

See Amchem, 521 U.S. at 623; In re Warfarin, 391 F.3d at 527. Significantly, the predominance requirement "is far more demanding" than the commonality requirement of Rule 23(a), which it incorporates. In re Warfarin, 391 F.3d at 527. Although common issues must predominate over individual inquiries, the existence of an individual inquiry does not preclude class certification, especially where all members face the necessity of proving the same fraudulent scheme. See In re Community Bank of Northern Virginia, 418 F.3d 277, 306 (3d Cir. 2005) (discussing Amchem, 521 U.S. at

³¹This element is the most contested by the parties. (<u>See</u> D.I. 382 at 1 (the central issue, with respect to class certification, is "whether impact of the alleged exclusionary conduct on, and the damages of, individual class members can be proven through class-wide evidence, or whether individual impact and damages issues will predominate."))

³²The Third Circuit also has recognized that monopolization and conspiracy claims involve predominantly common issues. See In re Warfarin, 391 F.3d at 528 (stating that allegations for violations of § 2 of the Sherman Act "naturally raise several questions of law and fact common to the entire class and which predominate over any issues related to individual class members, including the unlawfulness of [defendants'] conduct under federal antitrust laws . . ., the causal linkage between [defendants'] conduct and the injury suffered by the class members, and the nature of the relief to which class members are entitled."); In re Linerboard, 305 F.3d at 152 (finding violation of Sherman Act's § 1 conspiracy claim would predominantly involve common issues of fact and law, where the inquiry focused on defendants' actions, not individual class members).

625). Similarly, individualized damages calculations do not defeat a Rule 23(b)(3) certification if the predominance requirement is otherwise met. <u>Id.</u> at 305-06; <u>Chiang v. Veneman</u>, 385 F.3d 256, 273 (3d Cir. 2004).

Defendants set forth many variations of the same argument, which is that direct purchaser plaintiffs cannot demonstrate injury or damages in the form of overcharges; however, the inquiry at the class certification stage is not whether direct purchaser plaintiffs' theories are correct or ultimately will prove successful but, rather, whether the theories are common to the class, susceptible to class-wide proof, and predominate over individual issues. See Fed. R. Civ. P. 23(b)(3). Specifically, defendants assert that: (1) the direct purchaser plaintiffs' claims are not suitable to an "overcharge" theory; (2) the proposed DPP class' asserted damages methodology is flawed; (3) a "lost profits" case cannot be certified on the facts of this case; and (4) the proposed DPP class did not show that each class member was injured. (D.I. 190 at 12-22)

a. Overcharge theory

Defendants ask the court to deny class certification because plaintiffs' overcharge theory "makes no economic sense on the facts of this case, facts that Dr. Leitzinger simply ignored." (Id. at 12) In this regard, defendants argue that the proposed DPP class makes several fatal assumptions which preclude class certification, specifically: (1) Dr. Leitzinger, in his analysis, improperly assumed an overcharge applied; 33 (2) Dr. Leitzinger's identification of the overcharges that occurred

³³"And, lastly, assuming, as [p]laintiffs contend, that this impact involves an overcharge, I have been asked to determine whether overcharge damages can be calculated for the [c]lass as a whole on an aggregate basis using a reliable methodology." (D.I. 109, ex. B at 8)

in this case is flawed because his definition of overcharge assumes that each TRICOR® prescription in the actual world would have been either a TRICOR® purchase or an AB-rated generic purchase in the "but for" world;³⁴ (3) TRICOR® and an AB-rated generic equivalent are fungible; and (4) in the "but for" world, there would have been the same relative number of fenofibrate prescriptions.³⁵ (Id. at 12-13)

With respect to defendants' overall argument that an overcharge theory does not make economic sense, this determination is improper at the class certification stage.

See Howard Hess Dental Laboratories Inc. v. Dentsply, Intern., Inc., 424 F.3d 363, 379 n.12 (3d Cir. 2005) (declining to address defendants' argument that plaintiff's theory of violation made "no economic sense" on a motion to dismiss because summary judgment is the pre-trial mechanism to address such issues). Moreover, in order to resolve defendants' arguments regarding the second and third "assumptions," the court would need to engage in merits determinations, such as whether TRICOR® and an AB-

³⁴Dr. Leitzinger's three identified potential categories of overcharge are: (1) the actual price of TRICOR® compared to the "but-for" price of AB-rated generics ("brandgeneric purchasers"); (2) the actual price of TRICOR® compared to the "but-for" price of TRICOR® ("brand-brand purchasers"); and (3) the actual price of AB-rated generics compared to the "but-for" price of an AB-rated generic ("generic-generic purchasers"). (D.I. 190, ex. B at 16-17, 36-37)

³⁵This assumption relates to the amount of damages, rather than the fact of damage, and is discussed in more detail <u>infra</u>. <u>See Bogosian</u>, 561 F.3d at 455 ("If, in this case, a nationwide conspiracy is proven, the result of which was to increase prices to a class of plaintiffs beyond the prices which would obtain in a competitive regime, an individual plaintiff could prove fact of damage simply by proving that the free market prices would be lower than the prices paid and that he made some purchases at the higher price.").

rated generic are "fungible" and what the relevant market is.³⁶ The court declines to address the merits at this stage.

b. Antitrust violation

The proposed DPP class asserts that it can demonstrate an antitrust violation through common proof. (D.I. 107 at 26) Direct purchaser plaintiffs, to prove a violation of the Sherman Act § 2, must establish that: (1) defendants possessed monopoly power in the relevant market; and (2) defendants willfully acquired or maintained that power. See United States v. Grinnell Corp., 384 U.S. 563, 570-71 (1966). In order to demonstrate a violation of Sherman Act § 1, the direct purchaser plaintiffs must show: (1) the existence of a contract, combination or conspiracy; (2) a restraint on trade; and (3) an effect on interstate commerce. Weiss v. York Hospital, 745 F.2d 786, 812 (3d Cir. 1984). In this regard, the court finds that each putative class member, had they pursued their claims individually, would have been required to prove identical facts, such as defendants' monopoly power, exclusionary scheme, effect on interstate commerce, conspiracy, and unreasonable restraint of trade. Therefore, these common issues predominate over any individual issues relating to proof of an antitrust violation.

c. Impact and damages

The proposed DPP class also contends that proof of antitrust impact will involve predominantly class-wide proof. (D.I. 107 at 27) Proof of impact or fact of damage requires a showing of some loss in business or property due to defendants' antitrust

 $^{^{36}}$ These determinations are disputed and both parties have proffered expert testimony, with differing conclusions, on these topics. (See D.I. 434 at ¶ 2 (denying summary judgment on relevant market definition)

violations, i.e., a causal relationship. <u>See Zenith Radio Corp. v. Hazeltine Research</u>, <u>Inc.</u>, 395 U.S. 100, 114 n.9 (1969); <u>In re Linerboard</u>, 305 F.3d at 151. At the class certification stage, the court's concern is whether the direct purchaser plaintiffs **could** prove impact through class-wide evidence; not whether, in fact, they have. <u>See In re Linerboard</u>, 305 F.3d at 152 (noting that "the [c]ourt need not concern itself with whether [p]laintiffs can prove their allegations regarding common impact; the [c]ourt need only assure itself that [p]laintiffs' attempt to prove their allegations will predominantly involve common issues of fact and law").

The proposed DPP class asserts that common evidence is available to show that, absent defendants' conduct, (1) average prices paid by direct purchasers for fenofibrate would have been substantially lower and (2) all or nearly all class members would have either bought the generic at lower prices, or paid lower prices on branded fenofibrate, or both. (D.I. 107 at 29)

With respect to the direct purchaser plaintiffs' assertion that class-wide evidence is available to demonstrate that market prices for fenofibrate would have been substantially lower but for defendants' exclusionary scheme, Dr. Leitzinger has explained that class members would have: (1) substituted more lower priced generic versions of TRICOR® for at least some (and likely most) of their branded TRICOR® purchases; (2) paid less for branded TRICOR®; and (3) paid less for those volumes of generic fenofibrate that they actually bought. (D.I. 109, ex. B at 16-17, 36-37) To demonstrate this impact, the direct purchaser plaintiffs' intend to use scholarly economic literature, governmental studies and empirical evidence analyzing the market wide effects of unfettered generic competition on the prices and market shares of both

brand and generic drugs. (<u>Id.</u>, ex. B at 18-24) This evidence can demonstrate impact on a class-wide basis because it shows that the experience and effects of generic entry and of impaired generic entry: (1) follow a recognizable pattern; (2) have been tested and evaluated in peer-reviewed studies; and (3) exist and are felt market-wide. (<u>See id.</u>, ex. B at 9, 18-24) Direct purchaser plaintiffs also intend to rely on defendants' and generic manufacturers' internal projections concerning the economic effects of generic competition. (<u>See id.</u>, ex. B at 24-32)

Direct purchaser plaintiffs' third offer of proof to demonstrate impact through class-wide evidence is the transactional sales data for fenofibrate from defendants and Teva, as well as commercial sales and pricing data for a variety of other drugs. (See id., ex. B at 32-34) The transactional sales data, according to the direct purchaser plaintiffs, is common evidence of market impact and applicable benchmarks, which reflects market experience of (1) unfettered competition from AB-rated generics, and (2) the results of efforts to impede generic entry. (D.I. 107 at 32-33) Dr. Leitzinger offers a benchmark approach to demonstrate market impact on a class-wide basis, an acceptable method where, as here, it is claimed that defendants relied upon such evidence when constructing their alleged scheme. See In re Linerboard, 305 F.3d at 153-55 (finding a benchmark analysis that was supported by data could be effectively applied in an overcharge situation).

Defendants assert that TRICOR® prices would not have been lower in the DPP class's "but for" world and, therefore, the direct purchaser plaintiffs cannot demonstrate

impact.³⁷ (D.I. 382 at 3) Defendants' expert, Margaret E. Guerin-Calvert, opined that "the but-for price for TRICOR® would not have been lower than the actual price and (may well have been higher)." (D.I. 376, ex. 4 at ¶ 101) Direct purchaser plaintiffs, however, proffer Dr. Leitzinger's opinion, in which he stated that "generic competition is a broad and powerful instrument for bringing down prices. Typically, within a relatively short time period, unfettered generic competition converts the vast majority of the market to generic products carrying a price less than a third of what the brand used to command. The remaining few buyers that stay with the brand often do so because they are offered substantial discounts." (D.I. 109, ex. B at 17) Defendants' contention addresses the merits of the action and not whether plaintiffs' theory is susceptible to class-wide proof; consequently, the court declines to address defendants' argument in this regard.

Defendants also contend that, even if TRICOR® prices would have been lower in the "but for" world, it is impossible to determine, through class-wide proof, which class members would have continued to purchase TRICOR® rather than switching to a still lower priced generic fenofibrate or some other dyslipidemia therapy, such that class certification is precluded. (D.I. 382 at 3-4) Not only does this argument depend on the merits of direct purchaser plaintiffs' case but, with respect to impact, this assertion disregards the Third Circuit's statement that impact can be shown simply through proof that purchases were made at a higher price than would otherwise have pertained but

³⁷Defendants do admit that those members of the proposed DPP class who can show that they would have purchased TRICOR® in the "but-for" world at a lower price, i.e., brand-brand purchasers, could present an overcharge theory. (D.I. 382 at 3)

for defendants' anticompetitive conduct.³⁸ See Bogosian, 561 F.2d at 455.

To some extent, direct purchaser plaintiffs rely on the <u>Bogosian</u> presumption to demonstrate that common evidence exists from which it can be shown that class members made some purchases at the higher price. (D.I. 107 at 34) That is, the direct purchaser plaintiffs claim they do not have to show that fact of injury actually exists for each class member; rather, the fact of injury can be presumed in these circumstances under <u>Bogosian</u>. (<u>Id.</u>) They assert that it is well recognized that a purchaser in a market where competition has been wrongfully restrained has suffered an injury. (<u>See id.</u> (citing <u>In re Warfarin</u>, 391 F.3d at 531)) More specifically, direct purchaser plaintiffs argue that all class members are, by definition, purchasers in a market and that abundant common evidence is available to show that defendants' conduct restrained competition in that market; therefore, common proof of impact has been established.³⁹

³⁸Defendants also argue that, even if TRICOR® prices would have been lower in the "but for" world, the impossibility of proving which class members are brand-brand purchasers precludes class certification. (D.I. 382 at 3-4) This argument relates to the quantum of damages and does not preclude class certification. <u>See Baby Neal</u>, 43 F.3d at 57.

³⁹In the alternative, the proposed DPP class contends that they have common evidence to demonstrate the three overcharges as identified by Dr. Leitzinger in the form of economic analyses, defendants' own documents and admissions, and other documentary evidence about the role of class members in the prescription drug distribution process. (D.I. 107 at 34) The direct purchaser plaintiffs also note that it is not necessary for them to show, at the class certification stage, that all members of the proposed class were affected because it is sufficient for them to demonstrate, as they have through Dr. Leitzinger's conclusions, that **nearly all** members of the proposed class were affected. (See D.I. 107 at 35; D.I. 109, ex. B at 10, 17) At this stage, the court considers it "appropriate to certify the class as currently defined while maintaining its authority later to amend the definition to exclude members who have not suffered injury because they would not have benefitted from reduced prices of [TRICOR®] or its generic equivalents." In re Relafen, 218 F.R.D. 344-36. The court also takes note of this authority, with respect to defendants' mitigation argument, in the event later

(<u>ld.</u>)

Defendants dispute this and argue, specifically, that in circumstances where "the actual prices of TRICOR® were not higher as a result of the alleged restraints than they would have been in the 'but for' world, defendants cannot be said to have received an overcharge as a result of their alleged violations." (D.I. 382 at 4) That is, defendants assert that direct purchaser plaintiffs must prove that all class members who would not have purchased TRICOR® in the "but for" world nevertheless would have continued to buy fenofibrate in a less expensive generic formulation. (Id. at 4) Defendants, however, enmesh the idea of a "but for" world with a "but for" price. Although potentially relevant to a number of the underlying predicates to their claims, direct purchaser plaintiffs only are required to show that they, in fact, did purchase TRICOR® at a higher price once an antitrust violation and causal relationship are established.

See Bogosian, 361 F.3d at 455.

Direct purchaser plaintiffs assert that their burden with respect to showing antitrust damages at the class certification stage is a limited one and rely upon aggregate damages as evidence of class-wide proof. (D.I. 107 at 36-37) In particular, Dr. Leitzinger concluded that it is feasible to calculate aggregate damages to the class

evidence demonstrates that individual issues predominate over common ones in this regard.

⁴⁰Specifically, defendants argue that "Abbott would have ceased its promotional activities in the "but for" world, thereby causing fenofibrate's share of the dyslipidemia market to shrink with the result that purchasers of TRICOR® in the actual world would have purchased other dyslipidemia therapies such as statins." (D.I. 382 at 4-5) This argument relies on two factual bases that are disputed: that the fenofibrate molecule sales would decrease in the absence of promotion by defendants and that TRICOR® 's price would have stayed the same or gone higher. (D.I. 249 at 12-14)

as a whole using class-wide and formulaic methodologies.⁴¹ (D.I. 109, ex. B at 36-40)

Defendants do not challenge Dr. Leitzinger's methodology as to the calculation of damages on a class-wide basis; rather, defendants assert that the court should evaluate predominance in the context of the showing that must be made for the proposed DPP class to recover. (D.I. 382 at 6 n.15) Defendants attempt to distinguish several of the cases relied upon by direct purchaser plaintiffs by arguing that the court, in each case, did not address whether plaintiffs had asserted a "proper" or "appropriate" measure of damages. As discussed above, the question, at this juncture, is not whether plaintiffs have asserted the "proper" or "correct" methodology but, rather, whether their asserted methodology can be shown on a class-wide basis. See Howard Hess, 424 F.3d at 379 n.12. Defendants are correct that the court must delve beyond the pleadings to assure itself that the requirements of Rule 23 are met; however, this inquiry is limited to the concerns of Rule 23 and not the ultimate success of the potential class' claims. 42 Based on the foregoing, the court concludes that common issue predominate over individual issues such that the predominance requirement is satisfied.

6. Superiority

⁴¹Even if there were a need to determine damages individually, the proposed DPP class correctly asserts that it would pose no barrier to class certification in this instance. See Bogosian, 561 F.2d at 456 ("[T]he necessity for calculation of damages on an individual basis should not preclude class determination when the common issues which determine liability predominate.").

⁴²Defendants, in addition to the above arguments, contend that class certification is improper on a "lost profits" theory; however, the court, having found that plaintiffs' theory of overcharges is appropriate at this juncture, declines to address defendants' assertions in this regard.

The superiority requirement asks the court to balance, in terms of fairness and efficiency, the merits of a class action against those of alternative available methods of adjudication. In re Prudential, 148 F.3d at 316. In the case at bar, denying certification would require each individual plaintiff to file suit individually, at the expense of judicial economy and litigation costs for each party. This action involves the resolution of numerous complex issues of law and fact common to all putative class members. As class certification provides an opportunity for the efficient resolution of the entire class in a single forum, the court concludes that the class action mechanism is a superior litigation approach.⁴³

B. Indirect Purchaser Plaintiffs

The proposed indirect purchaser plaintiffs' class ("proposed IPP class") is as follows: "All persons or entities throughout the United States and its territories who purchased, paid for and/or reimbursed for fenofibrate products, including TRICOR® tablets and TRICOR® capsules, intended for consumption by themselves, their families, or their members, employees, plan participants and beneficiaries or insureds during the period April 9, 2002 through such time in the future as the effects of defendants' illegal conduct, as alleged, have ceased." (Civ. No. 05-360, D.I. 251) The indirect purchaser plaintiffs ask the court to certify the proposed IPP class pursuant

⁴³The court also notes that class certification avoids the risk of inconsistent results, the potential for which exists if each individual plaintiff were to file suit.

⁴⁴Excluded from the class are all defendants and their respective subsidiaries and affiliates, all government entities (except for government-funded employee benefit funds), and all persons or entities that purchased fenofibrate products: (1) for purposes of resale; or (2) directly from any of the defendants. (Civ. No. 05-360, D.I. 251)

to Fed. R. Civ. P. 23(b)(2), which requires that "the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole." As discussed above, the court's order of this same date stays all non-federal claims and, consequently, the parties' arguments relating to non-federal claims are not addressed.

Numerosity is met in this instance because evidence of record indicates that millions of prescriptions were dispensed in the past several years, such that joinder is impracticable. (See Civ. No. 05-360, D.I. 119, exs. 46, 47) With respect to commonality, the indirect purchaser plaintiffs identify several common questions of law and fact that are similar to those identified by the direct purchaser plaintiffs and which the court finds sufficient to meet the commonality requirement. (See Civ. No. 05-360, D.I. 24 at ¶ 101) The claims of the proffered representatives, as identified in note 2 supra, are typical of the class as a whole because, as with the direct purchaser plaintiffs, the claims focus on the defendants' conduct. Adequacy also is satisfied, as there are no identified conflicts within the class and counsel possess the experience necessary to pursue the interests of the class. (See Civ. No. 05-360, D.I. 108) Lastly, the court is satisfied that it can fashion appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole, if necessary.⁴⁵

V. CONCLUSION

For the reasons stated above, the direct purchaser plaintiffs' motion for class

⁴⁵Defendants' objections to the indirect purchaser class are only with respect to their non-federal claims. (See Civ. No. 05-360, D.I. 211)

certification (D.I. 106) is granted. The indirect purchaser plaintiffs' motion for class certification (D.I. 116) is granted in part and denied in part.⁴⁶ An appropriate order shall issue.

⁴⁶The motion is denied without prejudice to the extent that the certified questions included the indirect purchaser plaintiffs' non-federal claims.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE		
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LTD.,)))	
Counterclaim Plaintiffs,)	
V.) Civ. No. 02-1512-SLR) (Consolidated)	
ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTE and LABORATOIRES FOURNIER S.A.,) (Oonsolidated))))	
Counterclaim Defendants.)	
IMPAX LABORATORIES, INC.,))	
Counterclaim Plaintiff,)	
٧.) Civ. No. 03-120-SLR) (Consolidated)	
ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTE and LABORATOIRES FOURNIER S.A.,))))	
Counterclaim Defendants.)	
IN RE TRICOR DIRECT PURCHASER ANTITRUST LITIGATION) Civ. No. 05-340-SLR) (Consolidated))	
IN RE TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION) Civ. No. 05-360-SLR) (Consolidated))	
	ORDER	

At Wilmington this 18th day of August, 2008, consistent with the memorandum opinion and order issued this same date;

IT IS ORDERED that:

- The direct purchaser plaintiffs' motion for class certification (Civ. No. 05-340,
 D.I. 106) is granted.
- 2. Pursuant to Fed. R. Civ. P. 23(c)(1)(B), the Direct Purchaser Class ("DP Class") is defined as follows:

All persons or entities in the United States who purchased TRICOR® in any form directly from any of the defendants at any time during the period April 9, 2002 through the present. Excluded from the DP Class are defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities.

- 3. Pursuant to Fed. R. Civ. P. 23(c)(1)(B), the court determines that the classwide claims and issues of the DP Class are as follows:
- a. Whether the conduct challenged by the DP Class as an "anticompetitive" scheme in the amended complaint (Civ. No. 05-340, D.I. 29) violated Sections 1 or 2 of the Sherman Act, 15 U.S.C. §§ 1, 2;
- b. Whether defendants' challenged conduct caused antitrust injury-in-fact to the DP Class, in the nature of overcharges;
- c. The quantum of overcharge damages, if any, owed to the DP Class in the aggregate under Section 4 of the Clayton Act, 15 U.S.C. § 4.
- 4. Louisiana Wholesale Drug Co., Inc., Rochester Drug Co-Operative, Inc., and Meijer, Inc. and Meijer Distribution, Inc. are hereby appointed representatives of the DP Class.
 - 5. Pursuant to Fed. R. Civ. P. 23(c)(1)(B) and 23(g), the following firms are

hereby appointed as counsel to the DP Class ("DP Class Counsel"):

- a. Liaison Counsel: Rosenthal, Monhait & Goddes, P.A..
- b. Lead Counsel: Garwin Gerstein & Fisher, LLP.
- c. Executive Committee members: Berger & Montague, P.C., Odom &

 Des Roches, LLP, The Smith Foote Law Firm, LLP, and Kaplan Fox & Kilsheimer, LLP.
- 6. By **August 25, 2008**, DP Class Counsel shall file with the court a motion seeking approval of a form and manner of notice that complies with Fed. R. Civ. P. 23(c)(2)(B).
- 7. The indirect purchaser plaintiffs' motion for class certification (Civ. No. 05-360, D.I. 116) is granted in part and denied in part.
- 8. Pursuant to Fed. R. Civ. P. 23(b)(2), the court certifies an Indirect Purchaser Class ("IP Class") defined as:

All persons or entities throughout the United States and its territories who purchased, paid for and/or reimbursed for fenofibrate products, including TRICOR® tablets and TRICOR® capsules, intended for consumption by themselves, their families, or their members, employees, plan participants and beneficiaries or insureds during the period April 9, 2002 through such time in the future as the effects of defendants' illegal conduct, as alleged, have ceased. Excluded from the IP Class are all defendants and their respective subsidiaries and affiliates, all government entities (except for government-funded employee benefit funds), and all persons or entities that purchased fenofibrate products: (1) for purposes of resale, or (2) directly from any of the defendants.

- 9. Pursuant to Fed. R. Civ. P. 23(c)(1)(B), the court determines that the classwide claims and issues of the IP Class are as follows:
- a. Whether the conduct challenged by the IP Class as an "anticompetitive" scheme in the complaint (Civ. No. 05-360, D.I. 24) violated Section 2 of the Sherman Act, 15 U.S.C. § 2;

- b. Whether defendants' challenged conduct caused antitrust injury-in-fact to the IP Class, in the nature of overcharges;
- c. Whether, if at all, the IP Class is entitled to injunctive relief under 15 U.S.C. § 26.
- 10. The court certifies the following as representatives of the IP Class: Cindy Cronin, Diana Kim, Sandra Krone, Alberto Litter, Neil and Helena Perlmutter, Elaine M. Pullman, Lula Ramsey, Charles M. Shain, Hector Valdes, Richard G. Wilde, Allied Services Division Welfare Fund, Sheet Metal Workers International Association Local Union 28, Painters' District Council No. 30 Health and Welfare Fund, Pennsylvania Employees Benefit Trust Fund, Philadelphia Federation of Teachers Health and Welfare Fund, and Vista Healthplan, Inc.
- 11. The IP Class' motion for the appointment of counsel (Civ. No. 05-360, D.I.107) is granted ("IP Class Counsel").
- 12. By **August 25, 2008**, IP Class Counsel shall file with the court a motion seeking approval of a form and manner of notice that complies with Fed. R. Civ. P. 23(c)(2)(B).

United States District Judge